



PATENT
Customer No. 22,852
Attorney Docket No. 07579.0015-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
)
Graham Edmund KELLY et al.)
) Group Art Unit: Not Yet Assigned
Serial No.: 10/600,004)
)
Filed: June 18, 2003) Examiner: Not Yet Assigned
)
For: CARDIOVASCULAR AND BONE)
TREATMENT USING ISOFLAVONES)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

NOTICE REGARDING RELATED LITIGATION

Applicants hereby notify the U.S. Patent and Trademark Office that a patent possibly related to the present application is involved in litigation. The present application, U.S.

Serial No. 10/600,004, filed June 18, 2003, is a continuation of U.S. application Serial No.

09/914,035, filed as PCT/AU00/00384 on April 27, 2000, which entered the national stage as on

December 10, 2001. The patent in suit, U.S. Patent No. 6,562,380, issued from U.S. application

Serial No. 08/910,837 on May 13, 2003, and was originally filed on August 13, 1997, as a

continuation of U.S. application Serial No. 08/338,567, filed January 12, 1995, now U.S. Patent No.

5,830,887. Although the instant application and the patent in suit do not share a common

specification or overlapping claims to priority, in the utmost of caution, the Applicants submit this

notice in the event that the disclosures in the respective specifications would be considered related.

Application Serial Nos. 10/600,004, 09/914,035; 08/910,837; and 08/338,567 are assigned to

Novogen Pty. Ltd. ("Novogen").

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STATUS OF RELATED LITIGATION

On June 3, 2003, Solae, L.L.C. ("Solae") filed a Complaint alleging that Archer Daniels Midland Company ("ADM") and Amerifit Nutrition, Inc. ("Amerifit") infringe at least one claim of U.S. Patent No. 6,562,380. The case, Civil Case No. 03-CV-732, was filed in U.S. District Court for the Eastern District of Missouri. The undersigned believes that Solae is the exclusive licensee of U.S. Patent No. 6,562,380 for products containing soy-derived isoflavones.

On June 23, 2003, ADM filed a Motion for extension of time to answer the Complaint until July 3, 2003. On June 26, 2003, the judge granted the Motion for extension of time to answer the complaint until July 3, 2003. On June 30, 2003, Amerifit filed a motion for extension of time to respond to the Complaint up to and including July 14, 2003. On July 3, 2003, ADM filed a motion to dismiss. On July 11, 2003, Amerifit filed a motion to dismiss. On August 11, 2003, Solae filed a response to the motions to dismiss. On August 14, 2003, Amerifit and ADM filed replies to Solae's response to the motions to dismiss. On August 26, 2003, Solae file a sur-reply to the motion to dismiss.

REMARKS

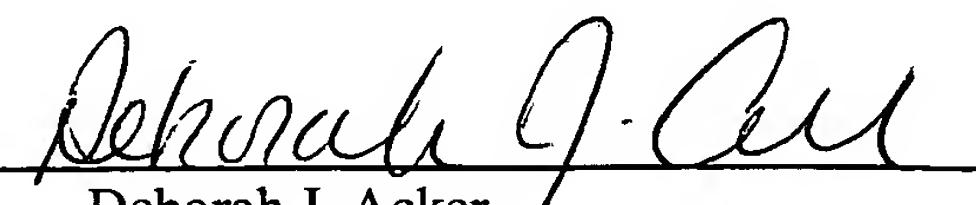
Further to this Notice Regarding Related Litigation, the Applicants submit a copy of the Complaint and a copy of the docket for Civil Case No. 03-CV-732, as of August 27, 2003.

If there are any fees due with the filing of this Notice not already accounted for, please charge the fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: September 10, 2003

By: 
Deborah J. Acker
Reg. No. 48,916

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

FILED

NOV 1991

U.S. DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

.....
SOLAE, L.L.C.

Plaintiff,

vs.

ARCHER DANIELS MIDLAND
COMPANY

and

AMERIFIT NUTRITION, INC.

Defendants.

SERVE DEFENDANTS AT:

(for Archer Daniels Midland Co.)
C T CORPORATION SYSTEM
120 South Central Avenue
Clayton, Missouri 63105

and

(for Amerifit Nutrition, Inc.)
CORPORATION SERVICE COMPANY
50 Weston Street
Hartford, Connecticut 06120
.....

4:036V00732HEA

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Solae, L.L.C. ("Solae" or "Plaintiff"), by its attorneys, for its Complaint against Archer Daniels Midland Company and Amerifit Nutrition, Inc. ("Defendants"), alleges and avers as follows:

JURISDICTION AND VENUE

1. This is an action for patent infringement arising under Title 35 of the United States Code, Chapter 28, Section 271 and Chapter 29, Section 281, *et seq.*
2. Upon information and belief, Defendants have committed infringing acts in this district and are subject to personal jurisdiction in this district.
3. Jurisdiction is conferred on this Court pursuant to 28 U.S.C. §§1331, 1332 and/or 1338(a).
4. Venue is proper in this district pursuant to 28 U.S.C. §§1391(a), (b), (c), 28 U.S.C. §1400(b), and E.D.Mo. L.R. 2.07(B)(3) and (4).

THE PARTIES

5. Plaintiff Solae, L.L.C. ("Solae" or "Plaintiff") is a Delaware limited liability corporation, having a principal place of business in St. Louis, Missouri.
6. Upon information and belief, defendant Archer Daniels Midland Company ("ADM") is a corporation organized under the law of Delaware, having its principal place of business at 4666 Faries Parkway, Decatur, Illinois 62526.
7. Upon information and belief, defendant Amerifit Nutrition, Inc. ("Amerifit") is a corporation organized under the law of Delaware, having its principal place of business at 166 Highland Park Drive, Bloomfield, Connecticut 06002.

BACKGROUND

8. St. Louis-based Solae is a leader in the research, manufacturing and marketing of high-quality, soy-based ingredients and ingredient systems.
9. Isoflavones are bioactive chemicals found naturally in plants. Soy isoflavones exist in three main families: genistein, daidzein and glycitein. Four chemical forms of isoflavones known as aglucones, glycosides, malonyl conjugates, and acetyl conjugates are found within each family. Soybeans are the major food source of the naturally-occurring isoflavones genistein and daidzein.
10. In the production of commercial products such as soy protein concentrates, the focus has been to remove soy isoflavone compounds since they are associated with the bitter flavor of soybeans. In a conventional process for the production of a soy protein concentrate, extracted material containing soy isoflavones, is typically discarded. As a result, the extract from a conventional process is an inexpensive and desirable source of soy isoflavones.
11. Recent clinical research suggests that isoflavones contained in vegetable protein materials such as soybeans, are bioactive compounds that may provide various health benefits, including the reduction of cardiovascular risk factors, the amelioration of conditions caused by reduced levels of endogenous estrogen in women (e.g., menopause or premenstrual syndrome), and the inhibition of certain human cancer cells (e.g., breast and prostate cancer cells).

12. U.S. Patent No. 5,990,291, issued November 23, 1999 (Reexamination Certificate 5,990,291 C1, issued August 28, 2001) (copy attached as Exhibit A) ("the '291 patent") entitled "Recovery of Isoflavones from Soy Molasses," names Doyle Waggle and Barbara Bryan as inventors and lists as assignee Protein Technologies International, Inc. ("PTI").
13. U.S. Patent No. 6,562,380 issued May 13, 2003 (copy attached as Exhibit B) ("the '380 patent") entitled "Methods for Treating or Reducing Predisposition to Breast Cancer, Pre-Menstrual Syndrome or Symptoms Associated with Menopause by Administration of Phyto-Estrogen," names Graham Kelly as inventor and lists on its face Novogen Research Pty. Limited (New South Wales, Australia) as assignee.
14. On or about March 28, 2003, PTI was renamed and reincorporated as Solae. Solae is the sole and exclusive licensee of the '380 patent for products containing soy-derived isoflavones.
15. Upon information and belief, ADM manufactures and markets a product that infringes at least one claim of the '291 patent which product is known as Novasoy® ("Novasoy") and is a powdered compound extracted from soybeans containing naturally-occurring isoflavones.
16. Upon information and belief, ADM's Novasoy contains at least the soy isoflavones daidzein, genistein, and glycitein, their glucosides, and acetyl and malonyl esters.
17. Upon information and belief, ADM's Novasoy isoflavone material is marketed and sold by ADM in this district and throughout the United States.

18. Upon information and belief, ADM's Novasoy isoflavone material is marketed and sold by ADM to manufacturers for incorporation into health and/or dietary supplements that infringe at least one claim of the '380 patent and are marketed and sold in this district and throughout the United States.
19. Upon information and belief, Amerifit manufactures and markets a product that infringes at least one claim of the '291 patent and at least one claim of the '380 patent, which product is known as Estroven[®] ("Estroven") and is a health supplement containing Novasoy isoflavone material provided by ADM.
20. Upon information and belief, Amerifit's Estroven contains at least the soy isoflavones daidzein, genistein, and glycitein, their glucosides, and acetyl and malonyl esters.
21. Upon information and belief, Amerifit's Estroven is marketed and sold by Amerifit in this district and throughout the United States for alleviating symptoms associated with menopause.

FIRST CAUSE OF ACTION

PATENT INFRINGEMENT

22. Solae here repeats and incorporates by reference all the allegations of paragraphs 1 through 21 above.
23. By assignment from all joint inventors, PTI was the owner of the '291 patent and sole and exclusive licensee of the '380 patent, and, upon formation of Solae, Solae became

the owner of PTI's intellectual property rights relating to soy isoflavones, including those relating to the '291 and the '380 patents.

24. Upon information and belief, ADM has directly and/or contributorily infringed at least one claim of the '291 patent and at least one claim of the '380 patent in connection with making, using, offering to sell, selling, and/or importation of Novasoy. ADM will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.
25. Upon information and belief, ADM has knowingly induced others to infringe at least one claim of the '291 patent and at least one claim of the '380 patent in connection with making, using, offering to sell, selling, and/or importation of Novasoy. ADM will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.
26. Upon information and belief, ADM's infringement of the '291 and the '380 patents is knowing and willful.
27. Upon information and belief, Amerifit has directly and contributorily infringed at least one claim of the '291 patent and at least one claim of the '380 patent in connection with making, using, offering to sell, selling, and/or importation of Estroven. Amerifit will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.
28. Upon information and belief, Amerifit has knowingly induced others to infringe at least one claim of the '291 patent and at least one claim of the '380 patent in

connection with making and/or using of Estroven. Amerifit will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.

29. Upon information and belief, Amerifit's infringement of the '291 and the '380 patents is knowing and willful.

REQUEST FOR RELIEF

WHEREFORE, Solae prays that this Court enter judgment in its favor against the Defendants and grant the following relief:

- A. Permanently enjoin Defendants, their agents, successors and assigns and all persons acting on their behalf or within their control, from making, using, selling, or offering to sell, importing or otherwise engaging in acts of infringement of the '291 and the '380 patents;
- B. Award Plaintiff damages caused by Defendants' patent infringement as determined by the jury in this action;
- C. Award treble damages pursuant to 35 U.S.C. §284;
- D. Enter an order declaring this an exceptional case and awarding Plaintiff interest, costs and disbursements in this action, including reasonable attorneys' fees pursuant to 35 U.S.C. §285; and
- E. Award Plaintiff such further relief as the Court may deem just and proper.

DEMAND FOR A JURY TRIAL

Plaintiff hereby demands trial by jury of all issues so triable in this action.

DATED: June 3, 2003

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By: C. David Goerisch

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Attorneys for Plaintiff

U.S. District Court

Eastern District of Missouri (Eastern)

CIVIL DOCKET FOR CASE #: 03-CV-732

Solae, L.L.C. v. Archer Daniels Co., et al

Filed: 06/03/03

Assigned to: Honorable Henry E. Autrey

Jury demand: Plaintiff

Demand: \$0,000

Nature of Suit: 830

Lead Docket: None

Jurisdiction: Federal Question

Dkt# in other court: None

Cause: 28:1338 Patent Infringement

SOLAE, L.L.C.
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FTS 878-8375

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defendant

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DOCKET PROCEEDINGS

DATE #

DOCKET ENTRY

6/3/03 1 COMPLAINT; # Summons Issued: 2 # Days to Respond: 20 # Counts: 1 Disclosure of Corp Cert issued to: deft; jury demand exhibits attached: A-B (klk) [Entry date 06/03/03]

6/3/03 2 RECEIPT # S2003-007859 in the amount of \$ 150.00 for filing fee (klk) [Entry date 06/03/03]

6/3/03 3 TRACK INFORMATION STATEMENT filed by plaintiff Solae, L.L.C. track 3 preferred (klk) [Entry date 06/03/03]

6/3/03 4 DISCLOSURE of Corporation Interests Certificate Parent companies: E.I. du Pont de Nemours and Company and Bunge Ltd. Subsidiaries: So Good International, Fuji Protein Technologies, DuPont Shineway Louhe Protein Company Limited, and Solae do Brasil. Publicly held company: E.I. du Pont de Nemours and Company and Bunge Ltd. by plaintiff Solae, L.L.C. (klk) [Entry date 06/03/03]

6/3/03 5 NOTICE OF PRIVATE PROCESS SERVER; Process Server: Markell & Associates (klk) [Entry date 06/03/03]

6/3/03 -- REPORT on the filing or determination of an action regarding Patent (cc: form mailed to register) (klk) [Entry date 06/03/03]

6/4/03 6 MOTION by plaintiff Solae, L.L.C. for order to substitute exhibit a of the complaint filed 6/3/03 substituting exhibit a attached (mjm) [Entry date 06/05/03]

6/5/03 7 RULED DOCUMENT by Honorable Henry E. Autrey granting motion for order to substitute exhibit a of the complaint filed 6/3/03 [6-1] (cc: all counsel) (mjm) [Entry date 06/05/03]

6/11/03 8 RETURN OF SERVICE executed upon defendant Amerifit Nutrition on 6/10/03 by personal service by serving Luz Marquez (mjm) [Entry date 06/12/03]

6/12/03 9 RETURN OF SERVICE executed upon defendant Archer Daniels Co. on 6/4/03 by personal service by serving Bonnie Hunt, Registered Agent (mjm) [Entry date 06/13/03]

6/19/03 10 MOTION by plaintiff Solae, L.L.C. for attorney David F. Ries to appear pro hac vice (mjm) [Entry date 06/20/03]

6/19/03 11 RECEIPT # S2003-008389 in the amount of \$ 25.00 for Attorney admission for David L. Ries (mjm) [Entry date 06/20/03]

6/20/03 12 MOTION by plaintiff Solae, L.L.C. for attorney Patricia A. Carson to appear pro hac vice (mjm) [Entry date 06/24/03]

6/20/03 13 RECEIPT # S2003-008425 in the amount of \$ 25.00 for Attorney admission for Patricia Carson (mjm) [Entry date 06/24/03]

6/23/03 14 RULED DOCUMENT by Honorable Henry E. Autrey granting motion for attorney David F. Ries to appear pro hac vice

[10-1] (cc: all counsel) (mjm) [Entry date 06/24/03]

6/23/03 15 ATTORNEY APPEARANCE for plaintiff Solae, L.L.C. by David F. Ries (mjm) [Entry date 06/24/03]

6/26/03 16 ATTORNEY APPEARANCE for defendant Archer Daniels Co. by Stephen H. Rovak, Michael T. Marrah, Kirill Y. Abramov (mjm) [Entry date 06/26/03]

6/26/03 16 MOTION by defendant Archer Daniels Co. for extension of time to answer Plaintiff's complaint until 7/3/03 (mjm) [Entry date 06/26/03]

6/26/03 17 RULED DOCUMENT by Honorable Henry E. Autrey granting motion for extension of time to answer Plaintiff's complaint until 7/3/03 [16-1] (cc: all counsel) (mjm) [Entry date 06/26/03]

6/26/03 18 DISCLOSURE of Corporation Interests Certificate Parent companies: None Subsidiaries: See Attachment Publicly held company: None by defendant Archer Daniels Co. (mjm) [Entry date 06/27/03]

6/30/03 19 MOTION by defendant Amerifit Nutrition for an extension of time to respond to Plaintiff's complaint up to and including 7/14/03 (mjm) [Entry date 07/01/03]

6/30/03 20 RULED DOCUMENT by Honorable Henry E. Autrey granting motion for attorney Patricia A. Carson to appear pro hac vice [12-1] (cc: all counsel) (mjm) [Entry date 07/01/03]

6/30/03 21 ATTORNEY APPEARANCE for plaintiff Solae, L.L.C. by Patricia Carson (Entry of appearance received in Clerk's Office on 6/20/03-- Order admitting pro-hac signed 6/30/03) (mjm) [Entry date 07/01/03]

7/1/03 22 RULED DOCUMENT by Honorable Henry E. Autrey granting motion for an extension of time to respond to Plaintiff's complaint up to and including 7/14/03 [19-1] (cc: all counsel) (mjm) [Entry date 07/02/03]

7/2/03 39 RECEIPT # S2003-009526 in the amount of \$ 50.00 for Attorney Admission for Gary Greenburg and Annapoorni Sankaran (mjm) [Entry date 07/23/03]

7/3/03 23 Notice of Motion: Motion to Dismiss by defendant Archer Daniels Co. (mjm) [Entry date 07/08/03]

7/3/03 23 MOTION by defendant Archer Daniels Co. to dismiss Date Motion Received: 7/10/03 [23-1] w/ memo in support and declaration of David K.S. Cornwell in support of motion attached (mjm) [Entry date 07/15/03]

7/10/03 24 MOTION by plaintiff Solae, L.L.C., defendant Archer Daniels Co. for leave to submit motion to dismiss w/ proposed order and motion to dismiss, memo in support and declaration of David K.S. Cornwell attached. (mjm) [Entry date 07/11/03]

7/10/03 24 MOTION by plaintiff Solae, L.L.C., defendant Archer Daniels

Co. for extension of time for Plaintiff to file a response to motion to dismiss up to and including 8/4/03 and Defendant to file a reply in support of motion up to and including 8/14/03 w/ proposed order, motion to dismiss, memo in support and declaration of David K.S. Cornwell attached (mjm) [Entry date 07/11/03]

- 7/11/03 25 MOTION by defendant Amerifit Nutrition to dismiss Plaintiff's Complaint Date Motion Received: 7/11/03 (mjm) [Entry date 07/15/03]
- 7/14/03 26 RULED DOCUMENT by Honorable Henry E. Autrey granting motion for extension of time for Plaintiff to file a response to motion to dismiss up to and including 8/4/03 and Defendant to file a reply in support of motion up to and including 8/14/03 [24-1], granting motion for leave to submit motion to dismiss [24-1] (cc: all counsel) (mjm) [Entry date 07/15/03]
- 7/14/03 27 MOTION by defendant Amerifit Nutrition to withdraw the memo in support of motion to dismiss w/ corrected memo in support attached (mjm) [Entry date 07/15/03]
- 7/16/03 28 MOTION by plaintiff Solae, L.L.C. for additional time to file response to defendant Amerifit's Motion to dismiss (mjm) [Entry date 07/17/03]
- 7/17/03 29 MOTION by defendant Archer Daniels Co. for attorney Donald R. Banowit to appear pro hac vice (mjm) [Entry date 07/18/03]
- 7/17/03 30 MOTION by defendant Archer Daniels Co. for attorney Timothy J. Shea, Jr. to appear pro hac vice (mjm) [Entry date 07/18/03]
- 7/17/03 31 MOTION by defendant Archer Daniels Co. for attorney David K.S. Cornwell to appear pro hac vice (mjm) [Entry date 07/18/03]
- 7/17/03 32 RECEIPT # S2003-009440 in the amount of \$ 75.00 for Attorney Admission for Donald R. Banowit, Timothy J. Shea, Jr., and David K.S. Cornwell (mjm) [Entry date 07/18/03]
- 7/21/03 33 RULED DOCUMENT by Honorable Henry E. Autrey granting motion for attorney David K.S. Cornwell to appear pro hac vice [31-1] (cc: all counsel) (cel) [Entry date 07/21/03]
- 7/21/03 34 RULED DOCUMENT by Honorable Henry E. Autrey granting motion for attorney Timothy J. Shea, Jr. to appear pro hac vice [30-1] (cc: all counsel) (cel) [Entry date 07/21/03]
- 7/21/03 35 RULED DOCUMENT by Honorable Henry E. Autrey granting motion for attorney Donald R. Banowit to appear pro hac vice [29-1] (cc: all counsel) (cel) [Entry date 07/21/03]
- 7/21/03 36 RULED DOCUMENT by Honorable Henry E. Autrey granting motion for additional time to file response to defendant Amerifit's Motion to dismiss [28-1] Pltff granted until 8/4 to file opposition to Amerifit's motion and Amerifit is granted until 8/14 to file reply (cc: all counsel) (cel)

[Entry date 07/22/03]

7/22/03 37 MOTION by defendant Amerifit Nutrition for attorney Gary R. Greenburg to appear pro hac vice (mjm)
[Entry date 07/23/03]

7/22/03 38 MOTION by defendant Amerifit Nutrition for attorney Annapoorni R. Sankaran to appear pro hac vice (mjm)
[Entry date 07/23/03]

7/23/03 40 RULED DOCUMENT by Honorable Henry E. Autrey granting motion for attorney Gary R. Greenburg to appear pro hac vice [37-1] (cc: all counsel) (cla) [Entry date 07/25/03]

7/23/03 41 RULED DOCUMENT by Honorable Henry E. Autrey granting motion for attorney Annapoorni R. Sankaran to appear pro hac vice [38-1] (cc: all counsel) (cla)
[Entry date 07/25/03]

7/25/03 42 DISCLOSURE of Corporation Interests Certificate Parent companies: None Subsidiaries: All subsidiaries are wholly owned by Amerifit Publicly held company: Jefferies, Inc., Fleet Bank and GlaxoSmithKline each are public companies which own ten percent (10%) or more of Amerifit through various private investment funds which they own or control by defendant Amerifit Nutrition (mjm) [Entry date 07/28/03]

8/4/03 43 MOTION by plaintiff Solae, L.L.C. for leave to file resp. to motion under seal w/ resp. attached (mjm)
[Entry date 08/05/03]

8/11/03 44 RULED DOCUMENT by Honorable Henry E. Autrey granting motion for leave to file resp. to motion under seal [43-1] (cc: all counsel) (mjm) [Entry date 08/11/03]

8/11/03 45 RESPONSE (memo in opp.) by plaintiff Solae, L.L.C. to motion to dismiss Plaintiff's Complaint Date Motion Received: 7/11/03 [25-1] w/ declaration of David F. Ries in support of resp. to mtn. attached (FILED UNDER SEAL) (mjm)
[Entry date 08/11/03]

8/11/03 45 SEALED DOCUMENT by plaintiff Solae, L.L.C. [45-1] (mjm)
[Entry date 08/11/03]

8/14/03 46 REPLY by defendant Amerifit Nutrition to response to motion to dismiss Plaintiff's Complaint Date Motion Received: 7/11/03 [25-1] (mjm) [Entry date 08/15/03]

8/14/03 47 REPLY by defendant Archer Daniels Co. to response to motion to dismiss Date Motion Received: 7/10/03 [23-1] [23-1] w/ exhs m-o attached (mjm) [Entry date 08/15/03]

8/25/03 48 MOTION by plaintiff Solae, L.L.C. for leave to file surreply under seal (mjm) [Entry date 08/26/03]

8/26/03 49 RULED DOCUMENT by Honorable Henry E. Autrey granting motion for leave to file surreply under seal [48-1] (cc: all counsel) (mjm) [Entry date 08/27/03]

8/26/03 50 SUR-REPLY by plaintiff Solae, L.L.C. to response to motion

to dismiss Plaintiff's Complaint Date Motion Received:
7/11/03 [25-1], motion to dismiss Date Motion Received:
7/10/03 [23-1] [23-1] w/ exh 19 attached (FILED UNDER SEAL)
(mjm) [Entry date 08/27/03] [Edit date 08/27/03]

8/26/03 50

SEALED DOCUMENT by plaintiff Solae, L.L.C. [50-1] (mjm)
[Entry date 08/27/03]

Case Flags:
AO120

END OF DOCKET: 4:03cv732

PACER Service Center			
Transaction Receipt			
08/29/2003 11:21:50			
PACER Login:	fh0018	Client Code:	07579-8050-00000/1322
Description:	docket report	Search Criteria:	4:03cv00732
Billable Pages:	7	Cost:	0.49